UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,359	07/15/2004	Domenico Fanara	2004_1045A	8158

513 7590 05/17/2007

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,359	FANARA ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed February 14, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made Non-Final.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejections)

1) Claims 1-9, 12, 14-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gowan (EP 0636,364). The rejection is maintained.

Applicant argues the reference discloses an example (Example 6) where cetirizine is mixed with cyclodextrine to form a complex, mixed with other ingredients and compressed to form an oral compositions. The compositions are a single formulation. The instant invention is to improve taste while avoiding stability impairment. The reference does not address this objective. Therefore the person skilled in the art would not be motivated to solve the problem and would be led away from the solution provided by the invention. Applicant further discusses the ways to taste mask the compound of formula I that have been disclosed in the prior art (see remarks pages 7-10). EP 0811374 A1 is also discussed and discloses mannitol and other polyols may create stability problems for compounds of formula 1. This argument is not persuasive.

The reference discloses the active ingredient is coated, therefore making it a separate formulation than the rest of the composition. The only requirement needed to

meet the limitations of the instant claims is the first formulation comprises the active ingredient and no polyol with a molecular weight less than 300. Nothing else has to be mixed with the active ingredient. The second formulation is the formulation outside of the coating. This includes compounds such as mannitol and is free of a compound of formula I, meeting the limitation of the instant claims. The Examiner is not sure where Example 6 is disclosed because it appears the instant reference does not disclose an Example 6. EP 0811374 further supports why one would choose one of the other ingredients over mannitol when adding these ingredient to the compositions comprising cetirizine. In regards to the purpose of the instant claims, the claims recite a formulation and make no mention of its properties such as taste-masking abilities and stability impairment. Therefore, the reference does not need to solve these problems although the coating is used as a taste masker (page 6, lines 34-38).

2) Claims 1-8, 12-15, 19-20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (US 6,627,234). The rejection is maintained.

Applicant argues the gum coatings may contain polyols and the examples disclosed by the 6,627,234 disclose a polyol as one of the components in the formulations. This argument is not persuasive.

The reference also discloses not only formulation with polyols but also formulations with sugar and no polyol. The polyol is an optional component in the active agent containing coating.

3) Claims 1-9, 12, 14-16 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fekete et al. (US 5,543,155).

Appliant argues the active layer of the two-layer tablet comprises a medicament, a hydrophilic polymer, filling material (cellulose, starch, lactose, mannitol), binding material and lubricant. This is contrary to the claimed invention wherein the first formulation does not comprise a polyol with a molecular weight of less than 300. None of the cited documents focus on the compounds of formula I therefore they do not solve the serious problem of taste caused by bitterness or stability loss in the presence of polyols. This argument is not persuasive.

The layer comprising the medicament may comprise cellulose, starch, lactose, or mannitol. Therefore mannitol is not necessarily present in the layer comprising the medicament. In regards to the bitterness or stability, as stated above, this is not a limitation of the instant claims, therefore, the references to not have to meet this limitation.

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

1) Claims 1, 3, 7-10, 14-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (EP 0 811 374).

Johnson et al. disclose compositions comprising a mixture of cetirizine and pseudoephedrine. The dosage form comprising a centirizine layer is free of alcohols having molecular weights lower than 100 and reactive derivatives thereof. The disclosed dosage forms comprise at least two formulations, one comprising centirizine in one

formulation and pseudoephedrine in the other formulation. The centirizine may be mixed with a water-soluble film-forming polymer. The centirizine compositions are used to coat the core of the tablets (page 5, lines 1-5). Alcohols having molecular weights of less than 100 react with centirizine and usually esterification occurs. The pseudoephedrine core component may comprise additives such as NaCl, KCl, $NaHCO_3$, lactose, sucrose, or mannitol and water-soluble polymers include HPC or HMPC or methylcellulose, encompassing claims 8-10. The core may also be coated with and impermeable coating (page 6, lines 6-20), encompassing claim 17. The reference anticipates the instant claims insofar as it discloses a two formulation tablet comprising a compound of formula I without a polyol having a molecular weight of under 300 and a second formulation comprising one or more polyols with a molecular weight of less than 3000 and comprises no compound of formula I.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fekete et al. (US 5,543,155) in view of Cupps et al. (US 6,172,095).

Fekete et al. disclose multilayer tablets wherein one layer comprises an active agent and the other a hydrophilic polymer. The active agents include cetirizine. The active layer may comprise tabletting fillers (such as e.g. cellulose, microcrystalline cellulose, lactose, mannitol, starch, dicalcium phosphate and the like), which, if desired, are then granulated in way known in the practice of tabletting, by using any of the processes described above. The other layer containing no active agent is prepared from

a 2% solution of HPMC having a viscosity higher than 1000 cP alone or together with 0 to 70% by weight of tabletting filler (such as e.g. cellulose, microcrystalline cellulose, lactose, mannitol, starch, dicalcium phosphate and the like), which, if desired, are then granulated in way known in the practice of tabletting, by using any of the processes described above. Subsequently, two-layer tablets containing the required amount of active agent in one layer and the required amount of HPMC in the other one, are prepared from the powder mixture of two kinds or, if desired, from the granulates prepared therefrom, which the lubricants needed had separately been mixed to by applying the second tablet core layer to the first one (cols. 8-11). The reference differs from the instant claims insofar as it does not disclose using sodium citrate in the multilayer tablet compositions.

Cuppes et al. disclose sodium citrate is used for a buffer in tablet compositions. These compositions may also comprise cetirizine. The reference differs from the instant claims insofar as it does not disclose two formulation compositions comprising a compound of formula I.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used sodium citrate or another alkalinizing agent in the compositions of

the primary reference motivated by the desire to use a compound for its known buffering function, as disclosed by the secondary reference and supported by cited precedent.

2) Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fekete et al. (US 5,543,155) in view of Dobrozsi (US 6,319,513).

The primary reference, Fekete et al., is discussed above in subsection 1. The reference differs from the instant claims insofar as it does not disclose using sodium citrate in the multilayer tablet compositions.

Dobrozsi disclose sodium citrate is used to provide consistent dispersion of solid particles thereby improving stability in oral compositions. The reference differs from the instant claims insofar as it does not disclose a two formulation composition comprising a compound of formula I.

See Sinclair & Carroll Co. v. Interchemical Corp., In re Linder, 457 F.2d 506, 507 (CCPA 1972); and also In re Dial, 326 F.2d 430, 432 (CCPA 1964) cited above. It would have been obvious to one of ordinary skill in the art to have used sodium citrate or another alkalinizing agent in the compositions of the primary reference motivated by the desire to use a compound for its known stabilizing functionality, as disclosed by the secondary reference and supported by cited precedent.

Claims 1 and 3-22 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614